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**STATE OF DELAWARE**  
**BOARD OF PHARMACY**

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<b>PUBLIC MEETING NOTICE:</b>	<b>BOARD OF PHARMACY</b>
<b>DATE AND TIME:</b>	<b>Wednesday, January 21, 2015 9:30 am</b>
<b>PLACE:</b>	Conference Room A, 2 <sup>nd</sup> Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
<b>APPROVED:</b>	February 18, 2015

**MEMBERS PRESENT**

Susan Esposito, R.Ph., Professional Member, Vice President  
Kimberly Robbins, R.Ph., Professional Member  
Bonnie Wallner, R.Ph., Professional Member  
Tejal Patel, PharmD, Professional Member  
Hooshang Shanehsaz, R.Ph., Professional Member  
Julia Wheatley, Public Member  
Jay Galloway, Public Member

**MEMBERS ABSENT**

Kenneth Sellers, Public Member, President  
Joli Martini, R.Ph., Professional Member

**DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

David W. Dryden, R.Ph., J.D., Executive Secretary  
Eileen Kelly, Deputy Attorney General  
Christine Mast, Administrative Specialist III  
Michelle McCreary, Pharmacist Compliance Officer

**ALSO PRESENT**

Lucy Somer  
Krista Alfonse  
Dennis Murphy  
Sean Whalen  
Tim Dillon  
Jaime Frink  
Phil Anderson  
Ann Campagna  
Suzanne Raab-Long  
Bill Harbester  
Brian Ricci  
Sasin George  
Nancy Sawyer  
Cheryl Heik  
Janes Levit  
Tiffany Sorey  
Kevin Morgan

### **CALL TO ORDER**

Ms. Esposito called the meeting to order at 9:35 a.m.

### **REVIEW OF MINUTES**

A motion was made by Ms. Robbins, seconded by Mr. Shanehsaz, to approve the meeting minutes for November 19, 2014 as amended. The motion unanimously carried.

### **PRESIDENT'S REPORT**

Ms. Robbins made a motion to defer the president's report due to absence; the motion was seconded by Mr. Shanehsaz. The motion unanimously carried.

### **UNFINISHED BUSINESS**

#### **Complaint Status**

13-09-11 – Assigned to Hearing Officer  
13-12-11 – Assigned to Hearing Officer  
13-19-11 – Forwarded to Office of Attorney General  
13-01-13 – Forwarded to Office of Attorney General  
13-04-13 – Forwarded to Office of Attorney General  
13-05-13 – Forwarded to Office of Attorney General  
13-06-13 – Forwarded to Office of Attorney General  
13-20-13 – Forwarded to Office of Attorney General  
13-26-13 – Assigned to Hearing Officer  
13-01-14 – Forwarded to Office of Attorney General  
13-03-14 – Assigned  
13-04-14 – Assigned  
13-05-14 – Assigned  
13-06-14 – Forwarded to Office of Attorney General  
13-07-14 – Forwarded to Office of Attorney General  
13-08-14 – Assigned  
13-09-14 – Forwarded to Office of Attorney General  
13-10-14 – Forwarded to Office of Attorney General  
13-11-14 – Forwarded to Office of Attorney General  
13-12-14 – Forwarded to Office of Attorney General  
13-13-14 – Assigned  
13-14-14 – Forwarded to Office of Attorney General  
13-15-14 – Assigned  
13-16-14 – Assigned  
13-17-14 – Assigned

#### **Public Hearing on Proposed Changes to Regulation @ 9:30 am**

Ms. Eileen Kelly, Deputy Attorney General called the hearing to order. Ms. Kelly asked the board members to introduce themselves for the record. Ms. Kelly explained the purpose of the meeting is to adopt proposed regulation amendments to Rule 5.1.14.3 and 14.1.1. Public notice was published in the register of regulations on January 1, 2015. Ms. Kelly had the following exhibits marked for the record: Board Exhibit 1, News Journal Affidavit of publication of the notice for today's hearing and Delaware State News Affidavit of publication of the notice for today's hearing. Ms. Christine Mast testified that no written comments had been received. There was no public comment. Ms. Kelly stated public comment will be open for another 15 days and written comment would also be accepted during that time. The board will hold deliberations at the next scheduled meeting. This concluded the hearing.

#### **Re-Review of Proposal to Deny**

None

#### **Proposal to Deny Hearing**

None

### Re-Review of Tabled Applications

Promptcare Home Infusion, a motion was made by Mr. Shanehsaz, seconded by Ms. Wallner to approve the application. The motion unanimously carried.

Par Sterile Products, a motion was made by Ms. Wallner, seconded by Mr. Shanehsaz to propose to deny the application. The motion unanimously carried.

### Final Denial of Application

Atlas Pharmacy, a motion was made by Ms. Robbins, seconded by Ms. Wallner to approve the final denial of the application. The motion unanimously carried.

Advantage Pharmacy LLC., a motion was made by Ms. Robbins, seconded by Mr. Shanehsaz to approve the final denial of the application. The motion unanimously carried.

### Review of Practitioner/Pharmacy Ownership

No Report

### Re-Review of CPR Course – Emergency University, Ca.

The board has determined that new pending regulations requiring “Hands On” instruction would disqualify this course for approval.

### DEA Federal Rules for Disposal

Mr. Dryden informed the board that the DEA has not yet provided guidance on guidelines for disposal. He will inform the board as they become available. This will be left as a standing agenda item.

### Feedback: Communication on Proposed Legislation

Mr. Dryden shared feedback from the Division Director, David Mangler and Cabinet Secretary, Jeffrey Bullock, regarding licensure and/or registration of pharmacy technicians. They shared the opinion that neither licensure nor registration can be supported at this time. The Division of Professional Regulation is not currently equipped to support this legislation systematically or operationally. In lieu of licensure, require a background check of all personnel who have access to the pharmacy area. This would be kept on file in the pharmacy for inspection purposes.

## **NEW BUSINESS**

Ms. Esposito read into the record the following ratifications.

### Pharmacist and Intern Licensure Approval Ratifications

<b>Pharmacist:</b>	A1-0004704	Michael P. Conti
	A1-0004705	Maureen A. Worrell
	A1-0004706	Mary Melissa Williams
	A1-0004707	Jackline G. Tawfik
	A1-0004708	Margaret Waithira Githara
	A1-0004709	Marie A. Callahan
	A1-0004710	Jill S. Extract
	A1-0004711	Sarah Ahmed
	A1-0004712	Mark E. Ciarlone
	A1-0004713	Kalee J. Olson
	A1-0004714	Robert Joseph Mullen
	A1-0004715	Jennifer Defnet

A motion was made by Ms. Robbins, seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

<b>Pharmacist Intern:</b>	A7-0002380	Kathleen Maria Seip
	A7-0002381	Akash Verma

A motion was made by Ms. Robbins, seconded by Ms. Patel to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001543	ARJ Infusion Services, Inc.
A9-0001544	Concierge Compounding Pharmaceuticals, Inc.
A9-0001545	Millennium Pharmacy Systems, Inc.
A9-0001546	Genoa Healthcare of New Jersey, LLC
A9-0001547	Sorkin's RX Ltd
A9-0001548	DermaTran Health Solutions
A9-0001549	Factor Support Network Pharmacy
A9-0001550	HMX Services, LLC
A9-0001551	HMX Services of New York, LLC
A9-0001552	Civic Health Services LLC, dba: Mt Hermon Discount Pharmacy
A9-0001553	Patient Direct Rx
A9-0001554	Independence Holding Company LLC
A9-0001555	Alero Health
A9-0001556	Rx Pro of Alabama, LLC
A9-0001557	Mesa Pharmacy, Inc.
A9-0001558	Irvine Wellness Pharmacy
A9-0001559	Total Vein Pharmacy
A9-0001560	Safe Pharmacy
A9-0001561	Rx To Go Pharmacy, LLC
A9-0001562	Isomeric Pharmacy Solutions LLC
A9-0001563	IPPC Inc. Pharmacy
A9-0001564	American Star Pharmacy
A9-0001565	Good Health, Inc.
A9-0001566	Primrose Pharmacy of PA, LLC
A9-0001567	Boca Raton Pharmacy, Inc.
A9-0001568	RXpress Pharmacy
A9-0001569	United Pharmacy Services LLC
A9-0001570	Lone Peak Professional Pharmacy
A9-0001571	Partners Pharmacy
A9-0001572	PBM Plus Mail Service Pharmacy, LLC
A9-0001573	Excelle Rx

A motion was made by Mr. Galloway, seconded by Mr. Shanehsaz to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001480	Hygen Pharmaceuticals, Inc.
A4-0001743	ProVen Pharmaceuticals, LLC-FL
A4-0001994	Medline Industries, Inc.
A4-0002138	Medline Industries, Inc.
A4-0002139	Hi-Tech Pharmacal Co., Inc.
A4-0002140	Bound Tree Medical, LLC
A4-0002141	Smiths Medical ASD, Inc.
A4-0002142	Asclemed USA, Inc
A4-0002143	Ceva Animal Health, LLC
A4-0002144	Exela Pharma Sciences, LLC
A4-0002145	DV Medical Supply, Inc.
A4-0002147	Norbrook, Inc.
A4-0002148	Sun Pharmaceutical Industries, Inc
A4-0002149	Proficient Rx LP
A4-0002151	H. D. Smith, LLC

A4-0002152 Specialty Therapeutic Care, LP  
A4-0002153 ProPharma Distribution, LLC.  
A4-0002154 Walgreen Co.  
A4-0002155 Perrigo Pharmaceuticals Company  
A4-0002156 Owen Laboratories, Inc.  
A4-0002157 Independent Pharmaceutical, LLC  
A4-0002159 Halyard Sales, LLC

A motion was made by Mr. Galloway, seconded by Mr. Shanehsaz to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

#### Medical Gas Dispensers

A2-0000053 Medstar Surgical & Breathing Equipment, Inc.  
A2-0000114 PromptCare, Inc

A motion was made by Mr. Galloway, seconded by Mr. Shanehsaz to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

#### Retail Pharmacy Licensure Approval Ratification

A3-0000850 Rite Aid #11175  
A3-0000845 Rite Aid #11187

A motion was made by Mr. Galloway, seconded by Mr. Shanehsaz to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

#### Retail Pharmacy Temporary Licensure Approval Ratification

None

#### Outsourcing Facility

AA-0000003 Leiter's Compounding  
AA-0000004 Exela Pharma Sciences, LLC  
AA-0000005 Healix Infusion Therapy, Inc.  
AA-0000006 AnazaoHealth Corporation

A motion was made by Mr. Galloway, seconded by Mr. Shanehsaz to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

#### Pharmacist-In-Charge Interviews

A motion was made by Mr. Shanehsaz, seconded by Ms. Patel to approve amending the agenda to add: Sean Whalen for PIC Interview. The motion unanimously carried.

Ms. Robbins conducted a PIC interviews with:

Dennis Murphy, Walgreens #11022  
Sean Whalen, Walgreens Newark, De.

#### Consultant Pharmacist Interviews

None

#### Board Review and Consideration of Consent Agreement

Robert Koch, a motion was made by Ms. Robbins, seconded by Mr. Shanehsaz, to approve the consent agreement as presented. The motion unanimously carried.

Timothy J Dillon, a motion was made by Ms. Robbins, seconded by Mr. Galloway, to table the consent agreement. The motion unanimously carried.

#### Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received, followed by the board ruling:

Facility: Biocure, LLC, a motion was made by Ms. Robbins, seconded by Ms. Wallner to approve the application. The motion unanimously carried.

Facility: Atlantic Biologicals Corp., a motion was made by Ms. Robbins seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Facility: CareKinesis, Inc. – NJ, a motion was made by Ms. Robbins, seconded by Mr. Shanehsaz, to approve the application. The motion unanimously carried.

Facility: CareKinesis, Inc. – CO, a motion was made by Ms. Robbins, seconded by Mr. Shanehsaz, to approve the application. The motion unanimously carried.

Facility: Hallandale Pharmacy, a motion was made by Mr. Galloway, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Facility: Virtus Pharmaceuticals, a motion was made by Ms. Robbins, seconded by Ms. Wheatley, to Table the application. The motion unanimously carried.

Facility: PharMedium Services, LLC (TX), a motion was made by Ms. Wallner, seconded by Ms. Robbins, to Table the application. The motion unanimously carried.

Facility: PharMedium Services, LLC (NJ), a motion was made by Ms. Wallner, seconded by Ms. Robbins, to Table the application. The motion unanimously carried.

Facility: PharMedium Services, LLC (MS), a motion was made by Ms. Wallner, seconded by Ms. Robbins, to Table the application. The motion unanimously carried.

Facility: PharMedium Services, LLC (TN), a motion was made by Ms. Wallner, seconded by Ms. Robbins, to Table the application. The motion unanimously carried.

#### Review of Hearing Officer Recommendation

Rockwell Compounding Associates, A9-0000638, a motion was made by Mr. Shanehsaz, seconded by Ms. Wallner, to approve the Hearing Officer Recommendation as presented. The motion unanimously carried.

#### Review of Crimes Listing For Discussion

Ms. Kelly has not completed the needed research and asked to keep this on the agenda.

#### Review of CE Received

Richard H Margolin, this agenda item was stricken from the record, as it was resolved just prior to the meeting.

### **COMMITTEE REPORTS**

**Legislative** – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

No Report

**Continuing Education** – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

Mr. Dryden reported that the audit process is ongoing. Ms. Robbins asked why continuing education logs are not accepted without all of the certificates. Mr. Dryden explained that there are several different CE providers and the logs are not consistent with their information. Therefore, certificates are requested to ensure that all the requirements are met.

**Consumer Affairs** – Ken Sellers and Jay Galloway:

No Report

**Professional Liaisons** – Kim Robbins and Tejal Patel:

Ms. Robbins reported that she attended the general membership meeting on January 20<sup>th</sup>. Their convention is scheduled for May 11-13<sup>th</sup>. Bylaw changes were made to create an executive committee which will consist of

the President, Vice-President, Treasurer, and Secretary. DPS still has an Executive Director, Secretary and future President positions to be filled.

**Controlled Substance Liaisons** – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

Next meeting to be held January 28, 2015

**Prescription Safety Committee** – committee members to be selected by Mr. Sellers at the next scheduled meeting.

### **COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS**

**USP 795 & 797 Committee** – Sandy Robinson, Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Mr. Dryden provided the USP 795/797 Final Draft Regulation and Office Use Regulation Final Draft for the Boards review. Mr. Shanehsaz made a motion to accept the proposed regulations; the motion was seconded by Ms. Wallner. The motion unanimously carried. A public hearing will be scheduled for April 15, 2015.

**Pharmacy Technician Licensure Committee** – Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Susan Esposito and David Dryden:

Mr. Dryden presented the Board's request "for" the NABP Pharmacy Technician and Inspector data by state for review. Members of the board expressed concerns regarding the backlog of inspections and the inability to do routine inspections in a timely manner with the current staffing of only one inspector for both the Board of Pharmacy and Controlled Substance Committee laws and regulations for the entire State of Delaware. This presents public safety concerns. The Board requested Mr. Dryden to provide inspection and staffing information providing a breakdown of inspection services needed to provide adequate patient protection. This information will also be discussed in detail at the next technician licensure committee meeting. There will be a committee meeting scheduled for February 18, 2015. A motion was made by Mr. Shanehsaz to make the Secretary of State, Jeffrey Bullock and the Division Director, David Mangler aware of the Boards concerns regarding the need for an increased inspection staff. This would assist in preventing a backlog and to protect the public. The motion was seconded by Ms. Wallner. The motion unanimously carried.

**Collaborative Care Committee** – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

No Report

### **BOARD CORRESPONDENCE**

Board of Pharmacy PIC Self-Inspection Alert, hand out provided

Surescripts – Second Update Regarding Industry Progress in Implementing Electronic Prescribing for Controlled Substances, hand out provided.

### **EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim**

Mr. Dryden reported that he will be attending the NABP 111<sup>th</sup> Annual meeting May 16-19, 2015 he will be attending. The staff is currently working diligently on the CE audit that was due January 12<sup>th</sup>. Internal diversion issues are on the rise in community pharmacies and hospitals. There have been a couple of investigations conducted across agencies when these diversions are found. Self-inspection reports are due in February. The newly updated forms will be uploaded and available in a few days. Ms. Michelle McCreary informed the board that there will be several DEA inspections in the near future. Mr. Dryden explained that these inspections take about 1.5 days to complete. Ms. Nettesheim provided the board with PMP data that outlined the PMP mandatory registration law and the numbers of registrants. Practitioner Delegate access has been provided since September 2014. The numbers of queries are on the rise quarterly. Pharmacy software reporting changes are required for Medicaid recipients in order for PMP data to be accurate. We are attempting to contact them. An ALERT regarding this issue has been sent to Delaware pharmacies.

### **NEWSLETTER UPDATES**

Newsletter will be available the first of February.

### **OTHER BUSINESS BEFORE THE BOARD**

Inactive Status clarification - keep on agenda for more discussion Eileen Kelly DAG will provide more information during the next meeting.

Legality of Pharmacies Providing Kickbacks to Prescribers in Exchange for Referrals – a letter was provided to the board for review during the meeting on November 19, 2014. The board would like to keep this on the agenda for more discussion.

**PUBLIC COMMENT**

Mr. Phil Anderson of Walgreens recognized Mr. Don Holst and his untimely passing.

**NEXT SCHEDULED MEETING**

The next meeting is scheduled for February 18, 2015 at 9:30 Am., Conference Room A 2<sup>nd</sup> floor.

**ADJOURNMENT**

There being no other business before the board a motion to adjourn the meeting was made by Mr. Galloway, seconded by Ms. Patel at 12:13 pm.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast  
Administrative Specialist III  
Liaison, Board of Pharmacy